**REMARKS**

Claims 40-57 are pending. Claims 25 and 27-39 have been cancelled. New claims 40-57 have been added. Support for new claim 40 may be found at least in original claim 1; page 18, line 30 to page 19, line 1; and Examples 1-4 on pages 26-28 of the specification. Support for claims 41-57 may be found at least in the original claims as filed. The new claims do not introduce new matter.

I. *Interview Summary*

The undersigned and the Applicant wish to thank Examiner Fubara for the cordial and productive interview of July 21, 2009. The Examiner's helpful comments and suggestions were instrumental in preparing this Amendment. During the interview, Applicant, Applicant's representatives, and the Examiner discussed the reintroduction of a new claim almost identical to the allowable claim 1 presented in the Notice of Allowability dated May 4, 2007. The Examiner urged Applicant to introduce that new claim so that she would have a chance to consider it.

II. *The rejections under 35 U.S.C. § 112, first paragraph (written description) are moot*

Claims 25, 27-29, and 31-35 stand rejected under 35 U.S.C. § 112, first paragraph for the reasons set forth on pages 3 and 4 of the Office Action as allegedly failing to comply with the written description requirement. Specifically, the Patent Office alleges that "[t]he specification as originally filed does not envision diameters in the range of about 1 millimeter to about 3 millimeters" and that the addition of a 1-3 mm range for the diameter constitutes new matter. The Patent Office is also of the opinion that the features "plurality of encapsulated products" and "plurality of encapsulated caplets" were not envisioned in the application as originally filed.

Although Applicant disagrees with this rejection for the reasons set forth in the response filed February 19, 2009, Applicant has cancelled claims 25, 27-29, and 31-35. Accordingly, these rejections are moot. Applicant therefore respectfully requests withdrawal of these rejections.

III. *The rejections under 35 U.S.C. § 112, second paragraph are moot*

Claims 25, 27-35, 37 and 38 stand rejected under 35 U.S.C. § 112, second paragraph for the reasons set forth on page 5 of the Office Action as allegedly being indefinite. Applicant asserts that these rejections are moot in light of the cancellation of all of those claims. And to the extent that these rejections could apply to new claims 40-57, Applicant asserts that none of the new claims are subject to the clarity issues that the Patent Office raises in the Office Action.

IV. *The rejection under 35 U.S.C. § 103(a) is moot and the new claims are patentable*

Claims 25, 27-32, 34, and 35 stand rejected over U.S. Patent No. 6,197,828 to Jerussi *et al.* in view of U.S. Patent No. 5,283,065 to Doyon *et al.*, U.S. Patent No. 5,431,922 to Nicklasson or U.S. Patent No. 5,762,961 to Roser *et al.* Claims 25 and 33 also stand rejected over Jerussi in view of Doyon, Nicklasson, Roser and further in view of US2002/0015731 to Appel *et al.* or U.S. Patent No. 6,306,436 to Chungi *et al.* Although Applicant disagrees with the rejection over Jerussi, Appel and Chungi for the reasons set forth in the response filed February 19, 2009, Applicant has never the less cancelled claims 25, 27-32, 34, and 35. Accordingly, these rejections are moot. Applicant respectfully requests reconsideration and withdrawal of these rejections.

To the extent that the rejections could apply to new claims 40-57, Applicant asserts that none of the references that the Patent Office cites, including Jerussi, alone or in combination with Doyon, Nicklasson, Appel or Chungi, teach, suggest, or otherwise contemplate the pharmaceutical product as claimed herein.

Claim 40, the sole independent claim, is drawn to a pharmaceutical product in a compressed caplet form having a diameter and length each of from about 1 mm to about 7 mm. The product consists of a therapeutically-effective amount of a uniformly distributed pharmaceutical. The pharmaceutical is an antibiotic, an antiinfective, a cardiovascular therapeutic, a gastrointestinal agent, a psychotropic or mixtures thereof. The product also consists of at least one compressible material, which is sucrose, and at least one lubricating material in an amount of up to about 5% by weight of the product. Finally, the product consists of at least one binder which is povidone k30 or plasdone k29/32.

Jerussi discloses methods of preparing, and compositions comprising derivatives of (+) venlafaxine. The dosage forms may include tablets, caplets, troches, lozenges, dispersions,

suspensions, suppositories, ointments cataplasms, pastes, powders, dressings, creams, plasters, solutions, capsules, soft elastic gelatin capsules, and patches. The only teaching in Jerussi specifically regarding a compressed tablet or caplet is found in Example 7, beginning at the bottom of column 26 and running through column 27. The formulations described in Example 7 contain a pharmaceutical in the form of venlafaxine, a compressible material in the form of microcrystalline cellulose, and lubricating materials in the form of pregelatinized starch and magnesium stearate. However, there is no teaching in Jerussi of the feature "at least one lubricating material in an amount of up to about 5% by weight of the product," as recited in claim 40. Instead, the formulations described in Example 7 contain at least 29% by weight of a lubricating material. *See* page 8 of Response Under 37 C.F.R. § 1.111 filed March 31, 2006 (Exhibit A). In addition, there is neither a reason enunciated on the record to date nor a teaching or suggestion in Jerussi that limiting the amount of the lubricating material to 5% or less would be desirable. Applicant notes that on page 3 of the Office Action dated June 19, 2006 (Exhibit B), the Patent Office withdrew the rejections based on Jerussi at least because Jerussi did not teach "up to about 5% by weight" lubricant and/or that limiting the amount of the lubricating material to 5% or less would be desirable. Applicant asserts that even the combined teachings of Jerussi, Doyon, Nicklasson, Appel, and Chungi fail to teach the feature "at least one lubricating material in an amount of up to about 5% by weight of the product."

Jerussi also fails to teach a caplet which is compressible into a diameter and length of from about l mm to about 7 mm. In addition, there is neither a reason enunciated in the record to date nor set out in Jerussi why the claimed sizes would be desireable. Interestingly, the formulation described in Example 7 of Jerussi does not tablet. *See* Declaration of S. Rao Cherukuri under 37 C.F.R. § 1.132 submitted with the response filed March 31, 2006 and resumbitted herewith as Exhibit C. It only tablets when Jerussi's formulation is modified to include a high amount of talc. In contrast, the claimed formulation, with the claimed components, readily compresses into the claimed sizes.

Since Jerussi alone, or in combination with Doyon, Nicklasson, Appel, and Chungi, fails to teach the claimed pharmaceutical product consisting of among other components 5% or less of a lubricating material and having the claimed size, Applicant asserts that the cited references can not render the claimed pharmaceutical product obvious. Further, the Patent Office has not

furnished a reason why one of ordinary skill in the art would modify Jerussi and/or the other references of record to arrive at a product consisting of among other components 5% or less of a lubricating material and having the claimed size. Accordingly, the claimed pharmaceutical product is patentable over the cited art and the claims should be allowed.

## CONCLUSION

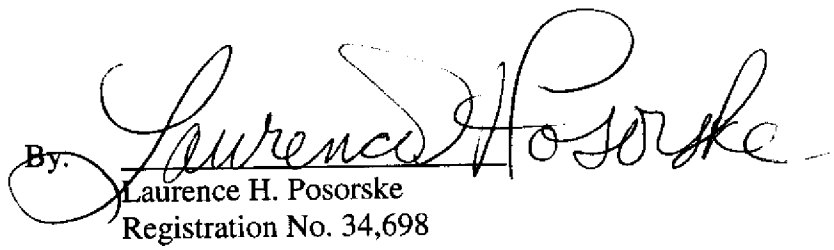
Entry of the foregoing and prompt and favorable consideration of the subject application on the merits are respectfully requested. Applicant respectfully submits that the pending claims are in condition for allowance.

The undersigned welcomes the Examiner to contact them at the telephone number provided below, especially if she believes that a telephonic interview may help further the prosecution of the instant application.

Respectfully submitted,

Hunton & Williams LLP

Date: July 24, 2009

By: 
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